AUG 3 0 2011

5. 510(k) SUMMARY

DATE: August 19, 2011

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500, ext. 2966

Contact: Angela J. Caravella, Regulatory Affairs Specialist
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DEVICE NAME: Introcan Safety® 3 Closed IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter

DEVICE CLASSIFICATION: Class II, per 21 CFR §880.5200: Intravascular Catheter

PREDICATE DEVICES: Introcan Safety® IV™ Catheter, B. Braun Medical, Inc., K021094 and K020785, Class II, DYB and FOZ, 880.5200: Intravascular Catheter

Nexiva™ Closed IV Catheter System, Becton Dickinson, K032843, Class II, FOZ, 880.5200: Intravascular Catheter

DESCRIPTION: The Introcan Safety® 3 Closed IV Catheter consists of an over-the-needle, peripheral intravascular catheter made of radiopaque polyurethane, an integrated bidirectional septum, a stabilization platform, and a passive safety needle-shielding mechanism.

The Introcan Safety® 3 will be offered in the following gauge sizes and lengths:

18ga x 1-3/4"	(45mm)
18ga x 1-1/4"	(32 mm)
20ga x 1-1/4"	(32mm)
20ga x 1"	(25mm)
22ga x 1"	(25mm)
24ga x ¾"	(19mm)

Introcan Safety® 3 design is described as a closed IV catheter since it protects clinicians and patients from blood exposure. Since the needle is withdrawn through a septum that seals after the needle has been removed, blood is thus contained within the Introcan Safety® 3 device. The pressure exerted on the needle as it passes through the septum wipes blood from the needle further reducing potential blood exposure.

The Introcan Safety® 3 catheter has an integrated stabilization platform is designed to improve catheter stability while minimizing catheter movement within the vessel.

The passive safety needle-shielding mechanism of the Introcan Safety® 3 is located inside the catheter hub. Upon withdrawal of the needle, the safety shield engages as the needle passes through the catheter hub and deploys automatically to shield the needle tip. The safety shield protects during disposal, aiding in the prevention of needlestick injuries. Once the safety shield engages and shields the needle tip, the user is unable to re-insert the needle which aids in the prevention of catheter shearing.

This device may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy

INTENDED USE:

The Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The 18-22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi with a luer lock connection only.

SUBSTANTIAL EQUIVALENCE:

Three predicate devices are utilized for substantial equivalence, B. Braun Medical Inc's Introcan Safety® (K021094 and K020785) and Becton Dickinson's Nexiva™ Closed IV Catheter System (K032843). Introcan Safety® 3 Closed IV Catheter has similar intended uses to B. Braun Inc.'s Introcan Safety®, in that they both act as an intravascular catheter that is inserted into a patient's vascular system for short term use (less than 30 days) to sample

blood, monitor blood pressure or administer fluids and blood intravascularly, the same passive safety needle-shielding feature is used to aid in the prevention of needlestick injuries, and some gauge sizes can be used with power injectors up to 300 psi.

Introcan Safety® 3 is similar to the Introcan Safety® , containing the same design elements, similar gravity flow rates, and intended uses with the only feature added is a valve that controls the flow of blood within the device until the catheter is attached to a luer compatible associated device such as an IV set, IV extension set, syringe, or filter which will engage the valve and allow for flow of fluid through the catheter.

Introcan Safety® 3 has a similar intended use to BD's Nexiva™ Closed IV Catheter System in that they both act as an intravascular catheter that is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly, they both contain a needle-shielding feature to aid in the prevention of needlestick injuries, blood is contained within the device to prevent blood exposure, both designs include a stabilization platform to reduce catheter movement within the vessel, they may both be used in any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure, and similar gauge sizes are suitable for use with power injectors rated for a maximum 300 psi and at a defined flow rate.

The Introcan Safety® 3 was developed to achieve a design that prevents the exposure of blood which matches the intended use of BD's Nexiva™ Closed IV Catheter System device. Each of the other intended uses for the Nexiva® are the same as the Introcan Safety® 3.

CONCLUSION:

Testing was conducted to demonstrate the performance of the Introcan Safety® 3 Closed IV Catheter and substantial equivalence with the predicate devices: B. Braun Medical Inc.'s Introcan Safety® and BD's Nexiva™ Closed IV Catheter System Closed IV Catheter System. The functional performance testing conducted with the proposed device demonstrates that the Introcan Safety® 3 Closed IV Catheter is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

B. Braun Melsungen AG
C/O Ms. Angela J. Caravella
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Bloulevard
Allentown, Pennsylvania 18109

AUG 30 2011

Re: K111236
Trade/Device Name: Introcan Safety® 3 Closed Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: August 19, 2011
Received: August 22, 2011

Dear Ms. Caravella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111236

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Introcan Safety® 3 Closed IV Catheter

Indications For Use:

Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly.

The 18-22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi with a luer lock connection only.

Prescription Use ___X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 8/30/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111236